INDUSTRY SURVEY REPORT

21 CFR 11
ELECTRONIC RECORD RETENTION

AWARENESS
CURRENT SITUATION
& PLANS

Prepared by
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(Addendum, 07 OCT 2002)

NOTE: On 07 OCT 2002, this report was submitted to the FDA for inclusion in the public docket:

00D-1536, "Electronic Records & Electronic Signatures, Retention of Electronic Records"

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1. Executive Summary

This survey was conducted to identify training and service needs for long-term retention of electronic records in FDA-regulated industries. Businesses included in the survey were manufacturers of pharmaceutical drugs, medical equipment, medical & dental instruments, medical & dental supplies, and ophthalmic goods.

The Hollis Group wanted to discover how familiar Quality Assurance and Regulatory Affairs personnel were with the details of 21 CFR 11, specifically their knowledge of the requirements and plans to retain, retrieve and read electronic raw data and electronic records.

Additional information was gathered to determine the level of awareness of the costs associated with the retention of records, both paper and other media. The estimated expertise in computer system validation was also compiled. Validation is a key requirement for the computer systems used to generate the original electronic raw data and records.

1.1. Survey Data

The telephone survey ran from September 30, 2000 to November 3, 2000.

The companies were selected based on data obtained from Dunn & Bradstreet, specifically SIC codes 283, 384, 385, which cover companies listing their primary business areas as pharmaceuticals, biotech products, medical devices, ophthalmic goods, dental supplies and x-ray equipment.

A total of 82 companies were contacted. Of those 35, or 43%, agreed to participate in the survey.

2. General Conclusions

1. The majority of those interviewed did not know the costs of retaining records. This applies to all types of records: paper, microfilm/microfiche, or electronic media. Most of the companies interviewed, 77%, expect to have to increase their budgets to retain, retrieve and read electronic records. However, of those who expect to increase their budgets, 57% have no idea how much their budgets will need to be increased.
2. All of the companies surveyed retain paper records. Companies maintaining electronic records most often use magnetic tape (77%) or floppies and CD's (73%), or both. The majority of the respondents are aware of the need to save electronic raw data; however, only about 50% are aware of the detailed requirements of 21 CFR 11 regarding the retention of electronic records.
3. Less than 25% of the companies surveyed have a written plan or policy for the long-term retention of electronic records. Approximately 50% are actively working on a plan, and the rest have not or do not intend to create a plan.
4. Of the persons interviewed, 63% were aware or very aware of the contents of either the plan in place or the in-process plan.
5. Of the companies that have or are working on a plan, all are wrestling with the technology to read data that has been retained. Most are struggling to create viable solutions for the short term. They say they may be OK today, but are not sure about their status in the future.
6. Approximately 20% of those interviewed did think that the ability to retrieve an electronic record was different than being able to read that electronic record. The rest believed these two actions were different; however, among this group the explanations of 'retrieve' and 'read' varied greatly.
7. Fewer than five (5) companies have explored the ability of existing technology to retain viable electronic records for up to several decades. Depending upon the industry's mandated record retention times, electronic records may need to be retained anywhere from 5 years to over 20 years.

8. A comparison of the Large (>$300M Annual Sales), Medium ($10-$300M) and Small (< $10M) participants revealed that the major difference lies in their knowledge of and familiarity with the regulation. Large companies tended to be more knowledgeable than the Medium-sized companies. Medium-sized companies were more knowledgeable than the Small companies.
9. When participants were asked if they would consider outsourcing functions associated with archiving, they responded as follows:
    1) 66% indicated they would or would consider outsourcing the long-term retention of electronic records.
    2) 63% indicated they would or would consider outsourcing the retention of operational configurations if they were required to retain them.
    3) 76% indicated they would or would consider outsourcing the conversion of old raw data to their current formats.
10. When participants were asked if they would consider using consultants on the project, they responded as follows:
    1) 83% indicated it would be valuable to very valuable to use a qualified consultant to assist in designing a solution.
    2) 90% indicated it would be valuable to very valuable to use a qualified contractor to implement the solution.
11. A comparison of the differences between Large (>$300M Annual Sales), Medium ($10-$300M) and Small (< $10M) companies revealed that there was no significant difference in the probability that they would outsource part or all of the retention of electronic records.

3. Survey Detailed Results

The survey results are divided into the following sections. Each section contains the graphical depictions of the results and in some cases, statistical data are included.

Demographics

This section describes the universe from which companies were contacted to participate in the survey. The parameters included geographic area, annual sales, and business lines.

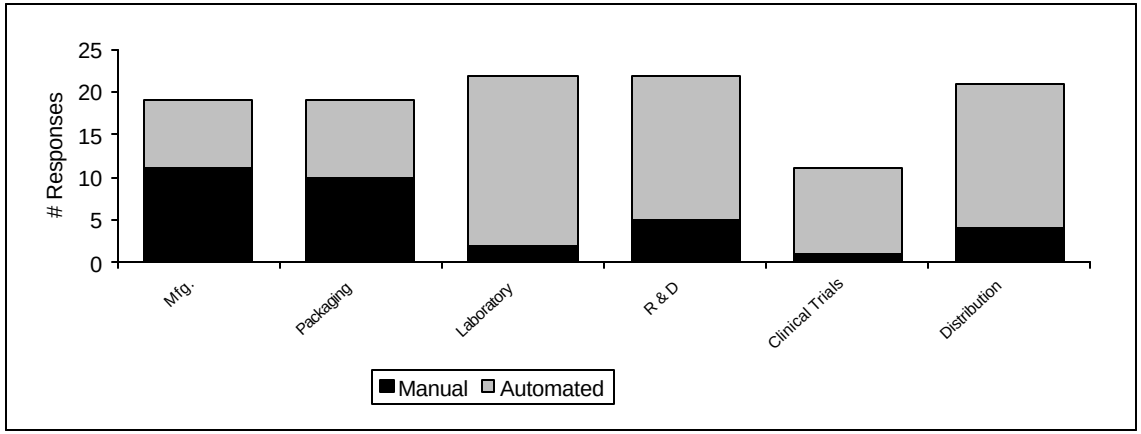
Companies Surveyed

The companies included in the survey were in the metropolitan areas surrounding Boston, New York, Philadelphia and Washington DC. The parameters used to select the companies to participate were Pharmaceuticals, Medical Devices and Biotechnology companies with annual sales between $2 – $300 million.[1] In addition, several major pharmaceutical companies were included (> $300 million in annual sales) to provide a contrast in perspectives.

Quality Assurance professionals were contacted to participate in the survey. In some cases, the interviewer was redirected to another individual within the company who was more knowledgeable about the regulation or project associated with compliance with the regulation.

Operations At The Surveyed Companies

Information was gathered about the types of operations that were performed within the company and if any of those activities were automated or computerized. This graph shows the types of operations and the breakdown of computerization/automation within each type.

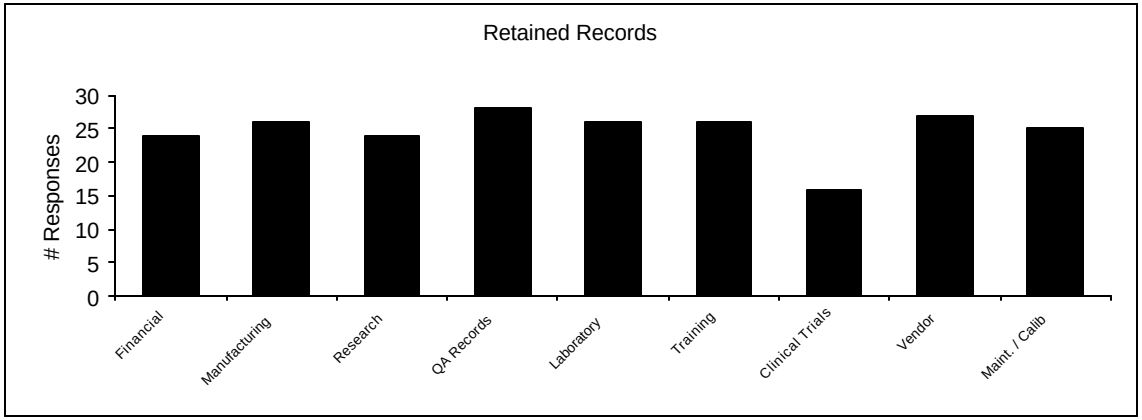


[1] Source: Dunn & Bradstreet.

Record Retention

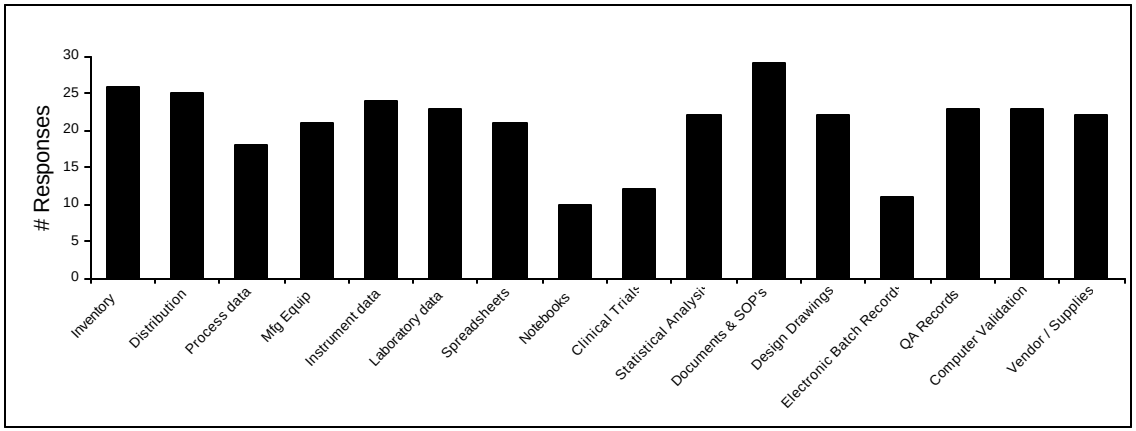
Record Types Retained

This graph shows the various types of records retained by the companies surveyed, regardless of the media on which those records were retained.



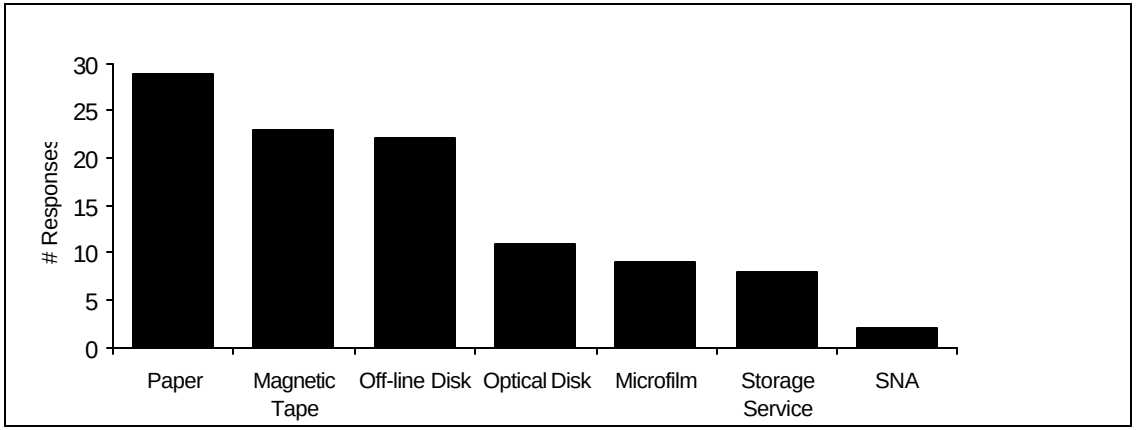
Electronic Records Types Retained

This graph shows the types of electronic raw data currently retained at the companies participating in the survey.



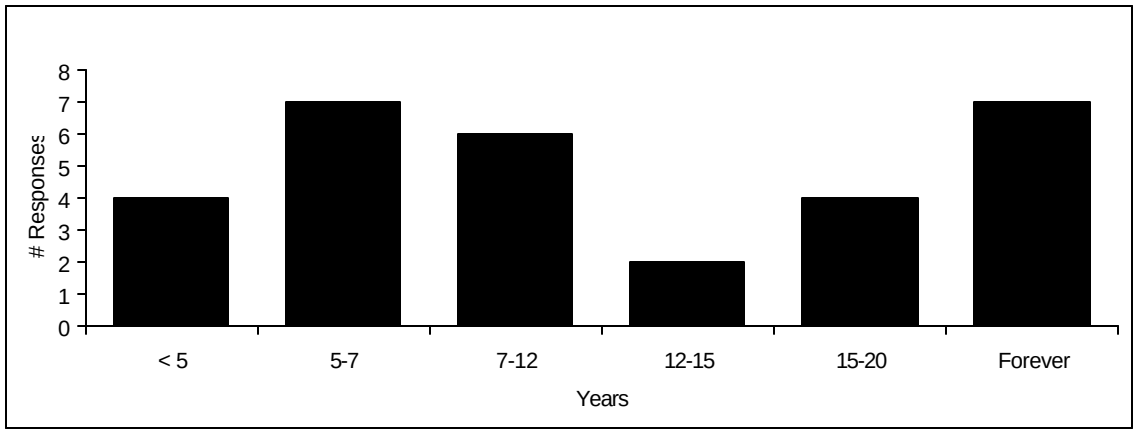
Media For Retention of Electronic Records

This graph shows the types of electronic media currently used by participating companies to retain information and records.



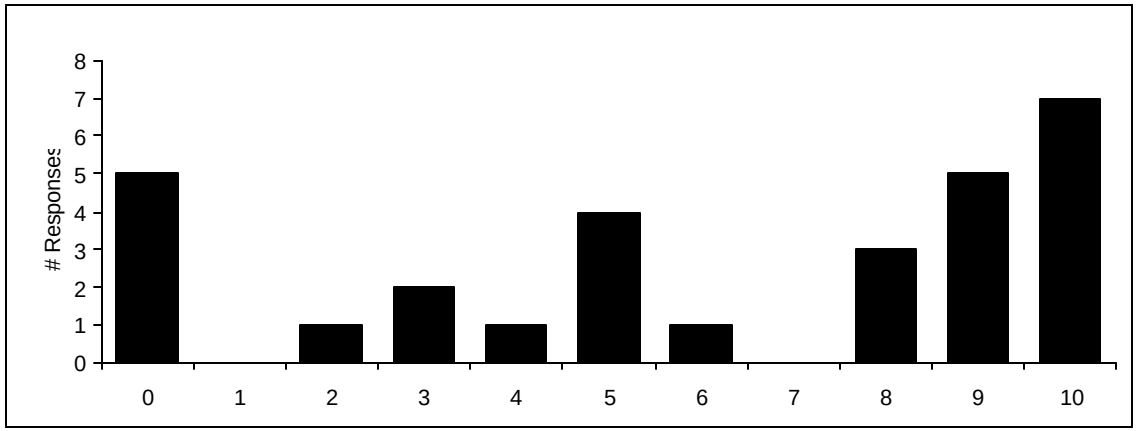
Retention Periods for Records

This graphs depicts how long responding companies retain their records.



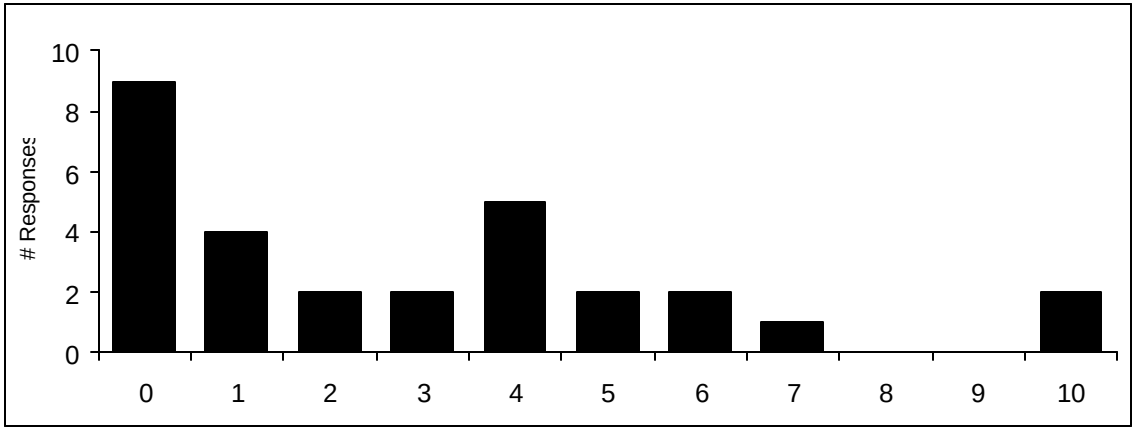
Retention Periods for Raw Date

This graph indicates the awareness of respondents of the length of time that raw data is required to be retained. On this scale, 0 = unaware and 10 = fully aware.



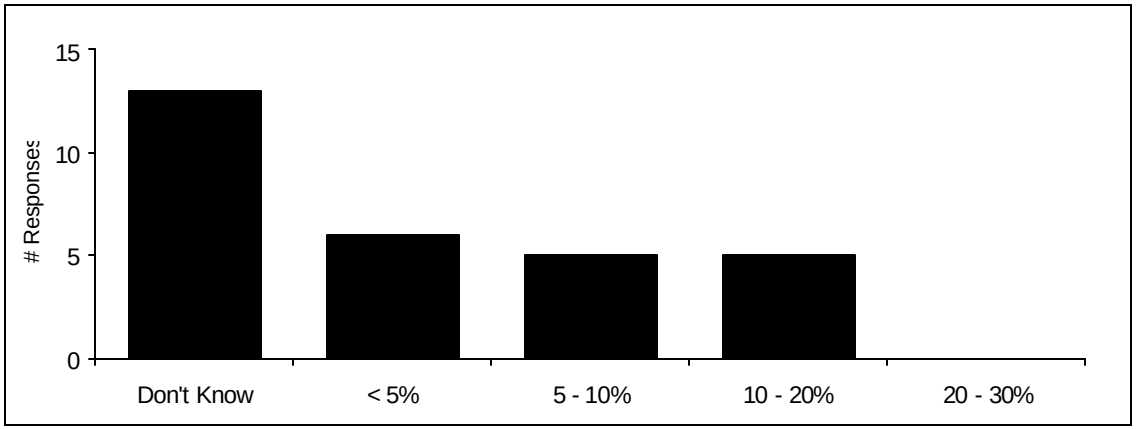
Awareness of the Cost to Retain Records

This graph shows respondents' awareness of the costs to retain records, regardless of the media on which those records were retained. On this scale, zero (0) indicates no knowledge of the cost, and 10 indicates the respondent was fully aware of the costs.



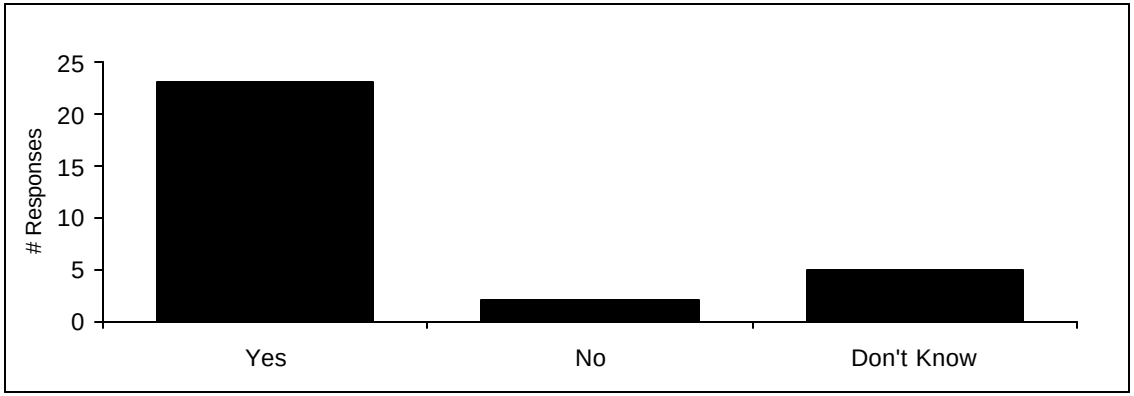
Estimated Cost to Retain Records

This graph shows how the respondents estimated the cost of retaining and maintaining records as a percentage of the Quality budget.



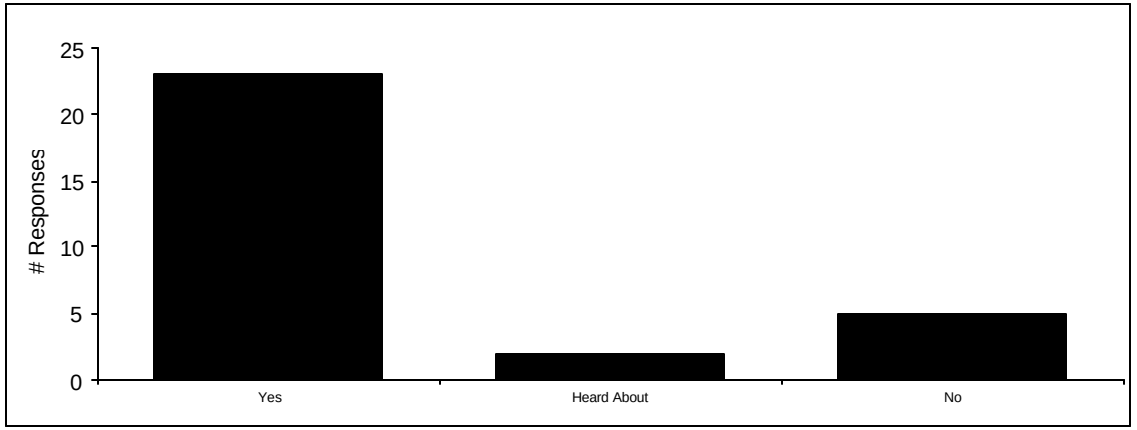
Impact Of 21 CFR 11 On the Cost of Retaining E-Records

The graph shows whether or not participating companies expect an increase in the cost of retaining electronic records. The individuals interviewed were unable to quantify the amount of the increase.

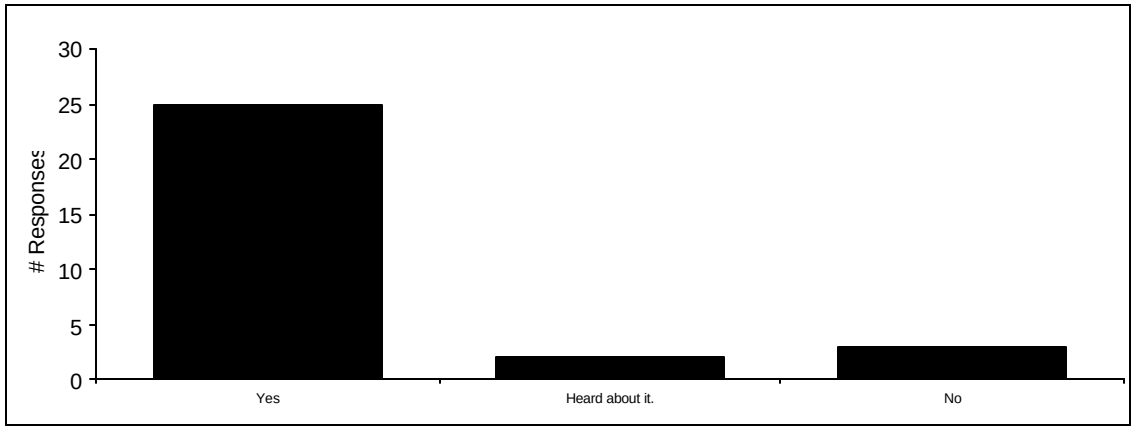


21 CFR 11 Awareness: Maintaining Electronic Records

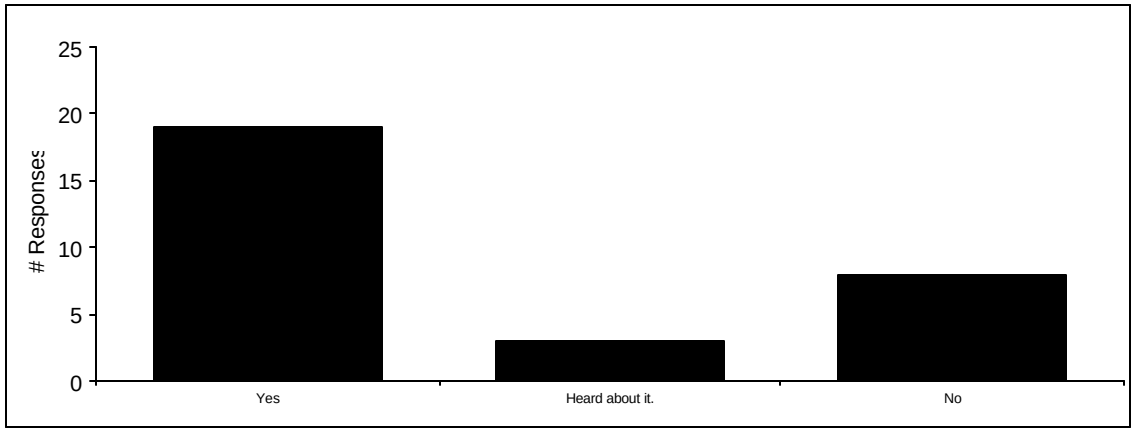
This graph shows the respondents' awareness that the regulation states that electronic Raw Data is an Electronic Record.



This graph shows the respondents' awareness that the regulation states that electronic raw data must be retrievable.



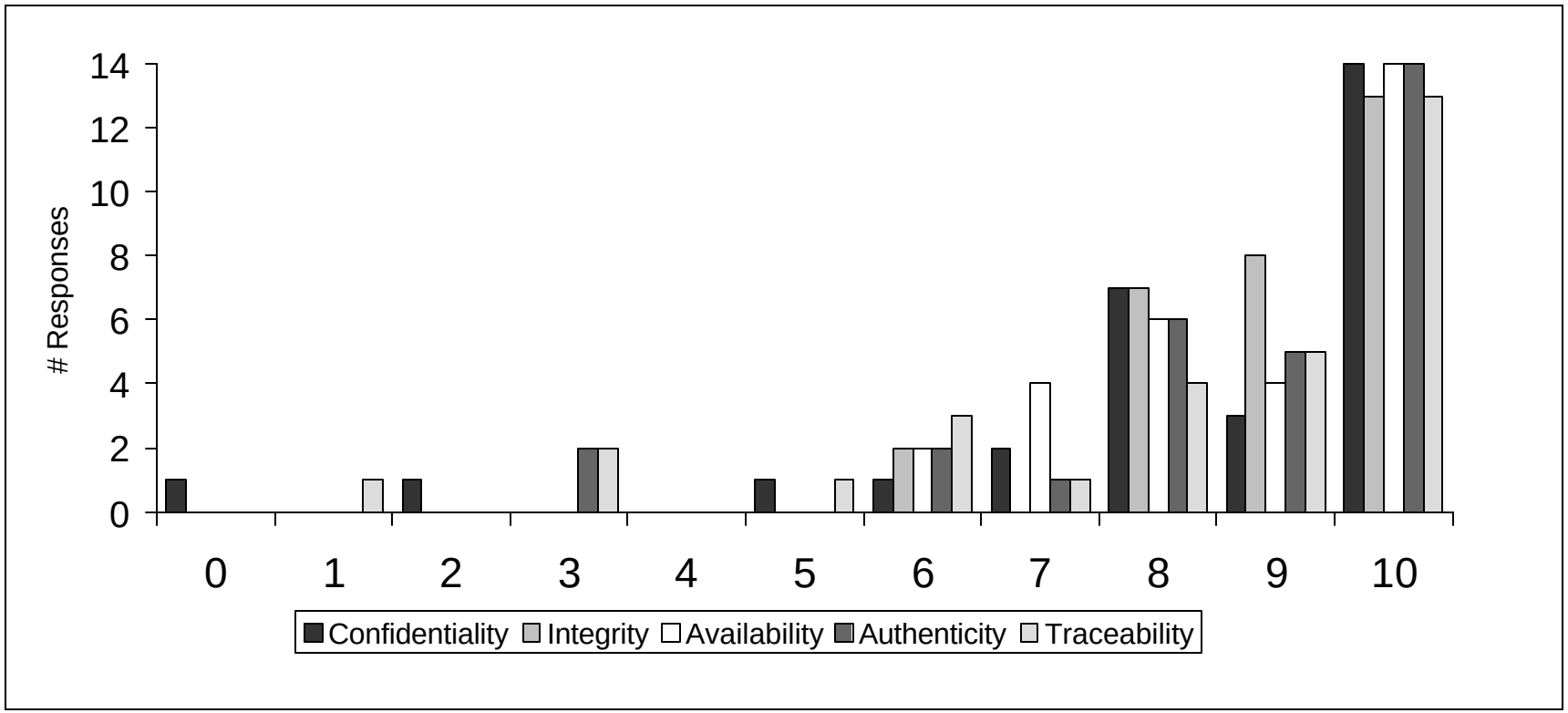
This graph shows the awareness of the respondents that the regulation states that electronic raw data must be readable.



Awareness Of The Details Of The Requirements For Electronic Raw Data

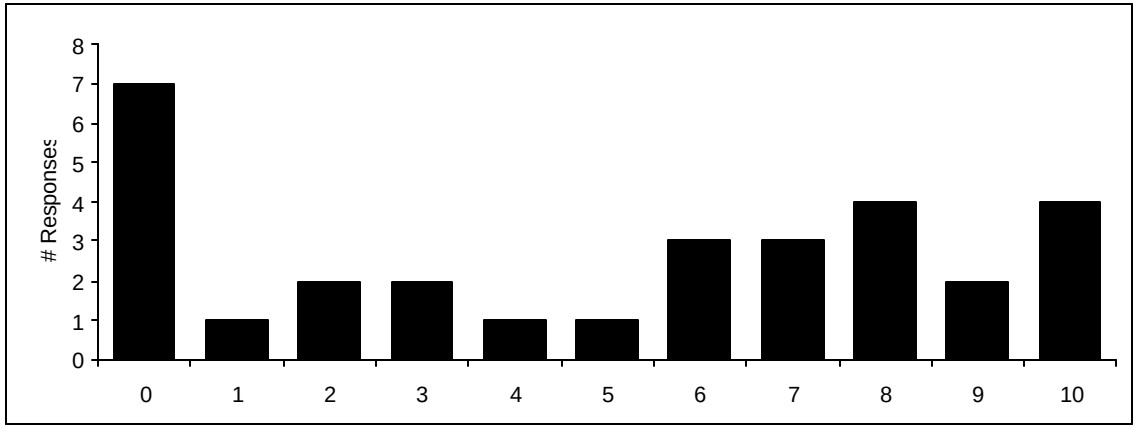
The professionals interviewed were asked to rate their awareness of the details in the section of 21 CFR 11 dealing with retention, retrieval and readability of electronic raw data and records. The scale is 0 – 10 where 0 = no knowledge and 10 = very knowledgeable.

This graph shows respondents' awareness of the details in the regulation about the confidentiality, integrity, availability, authenticity and traceability of electronic records and electronic signatures.

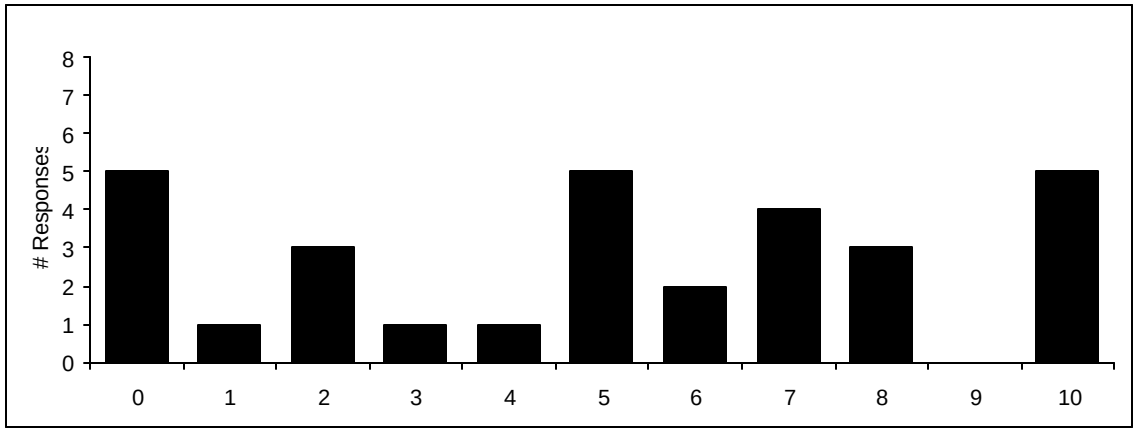


Awareness Of The Details Of The Requirements For Electronic Raw Data (continued)

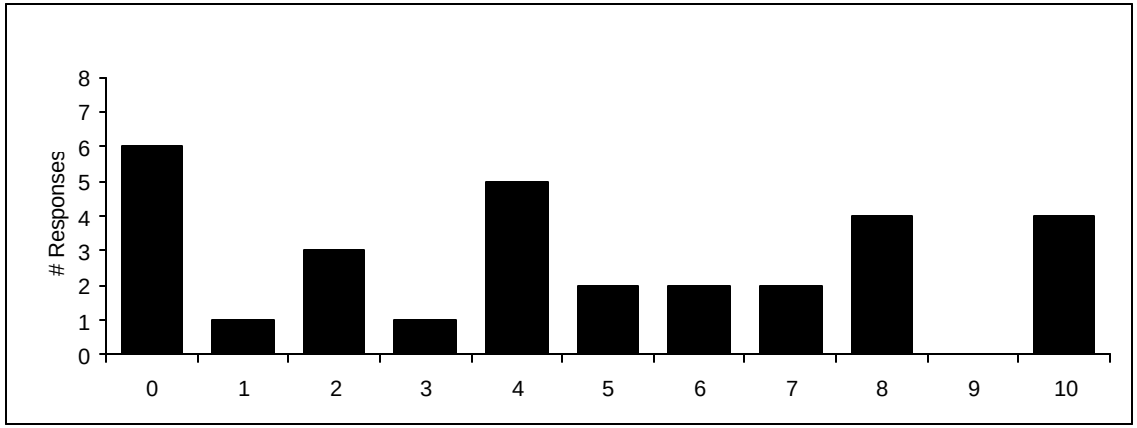
This graph shows respondents' level of awareness of the details in the regulation about the retention of electronic raw data. The scale used for all three of these graphs is 0 – 10 where 0 = unaware and 10 = very aware.



This graph shows respondents' level of awareness of the details in the regulation about the retrieval of electronic raw data.

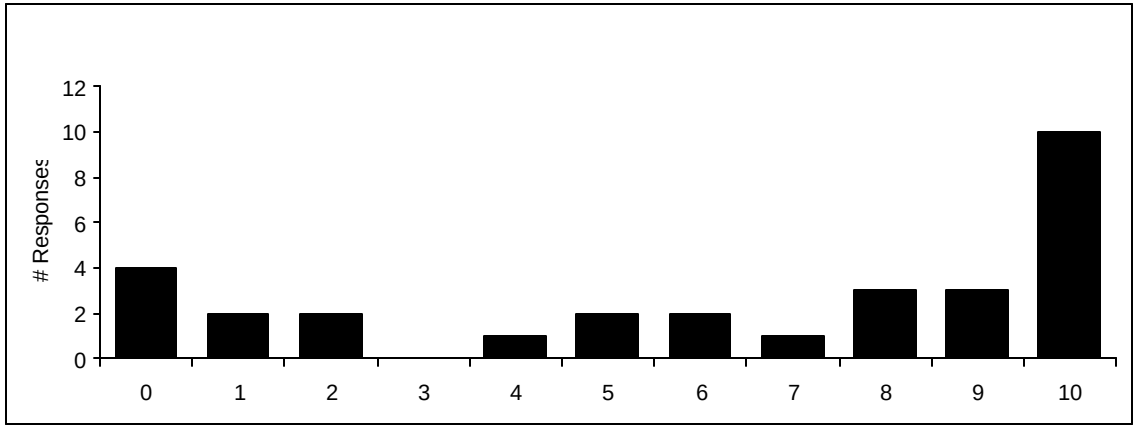


This graph shows respondents' level of awareness of the details in the regulation about reading the retrieved electronic raw data.

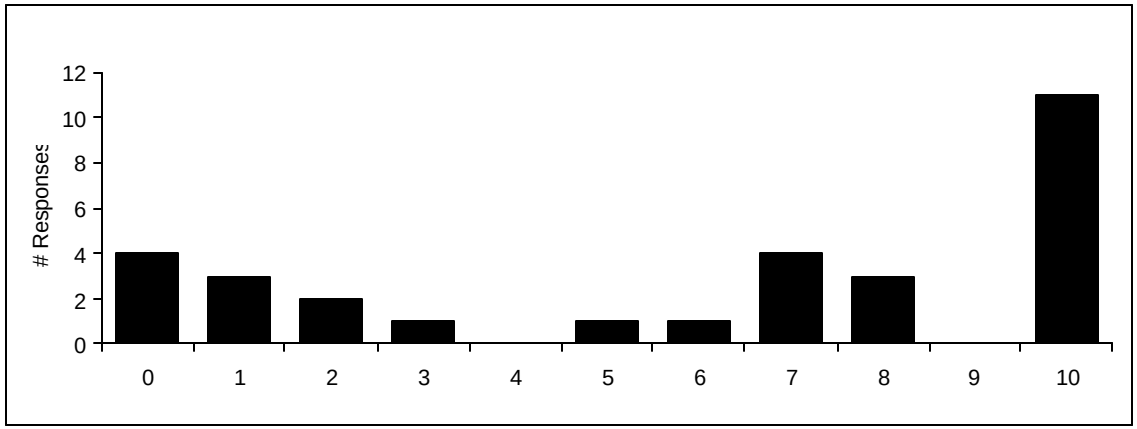


Awareness Of The Details Of The Requirements For Electronic Raw Data (continued)

This graph shows respondents' level of awareness of the details in the regulations about the retrieval of meta data or audit trails. The scale for both of these graphs is 0 – 10 where 0 = unaware and 10 = very aware.

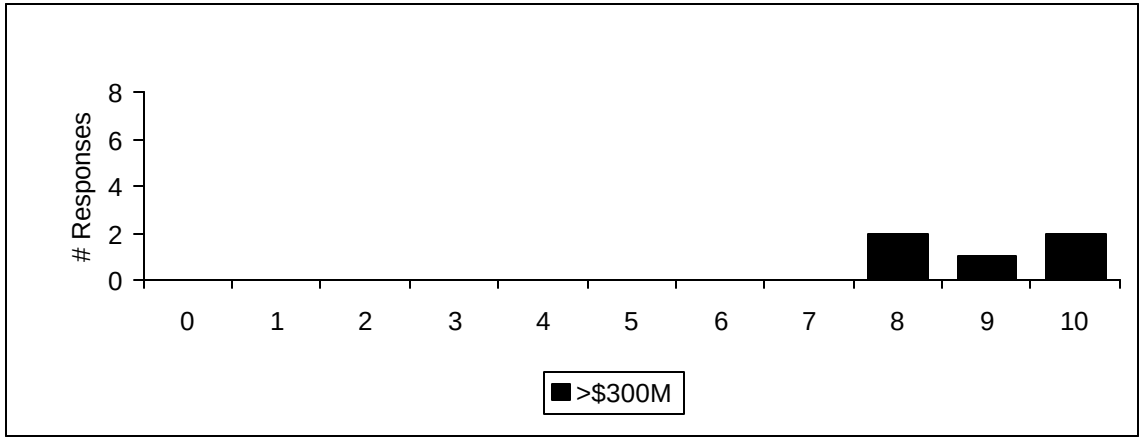


This graph shows respondents' level of awareness of the details in the regulations about reading the retrieved meta data or audit trails.

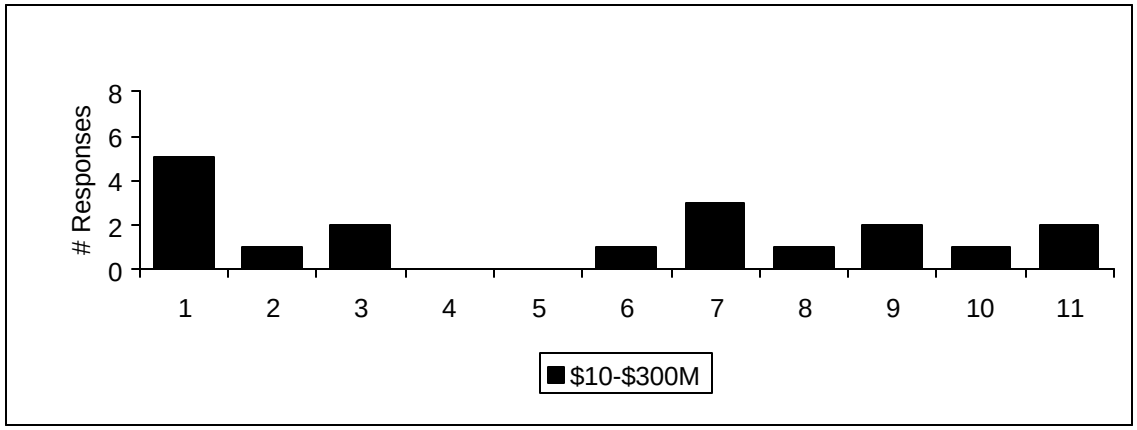


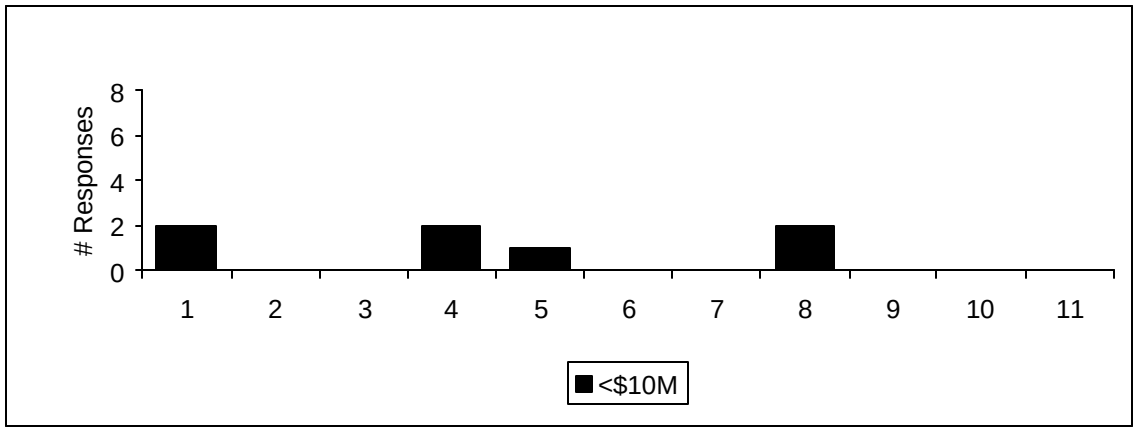
Awareness Difference By Company Size

Company size was related to the respondents' level of awareness of the regulation itself. The answers on awareness were on a scale of 0 – 10 where 0 is unaware and 10 is very aware.



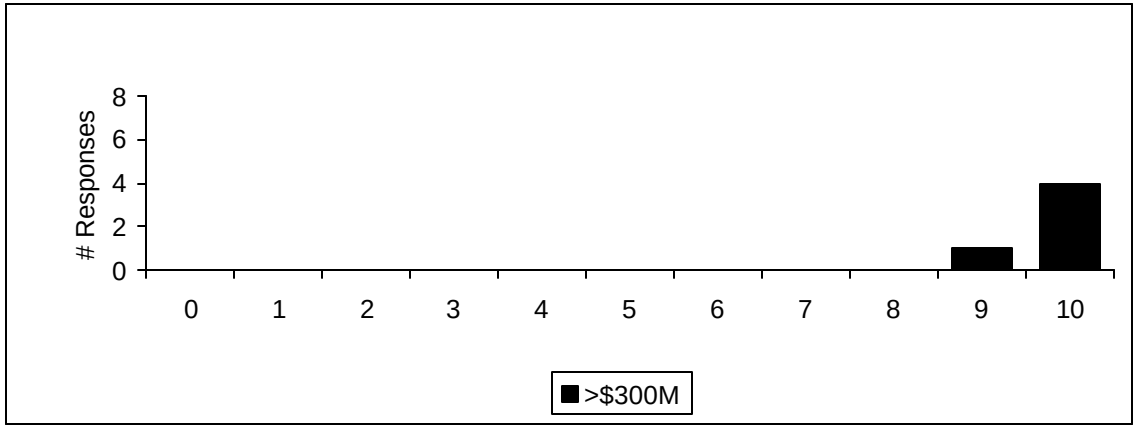
These three graphs show respondents' level of awareness of the details of the regulation's requirements for the retention of electronic raw data at Large (greater than $300 million in annual sales), Medium ($10-300 million) and Small (less than $10 million) companies.



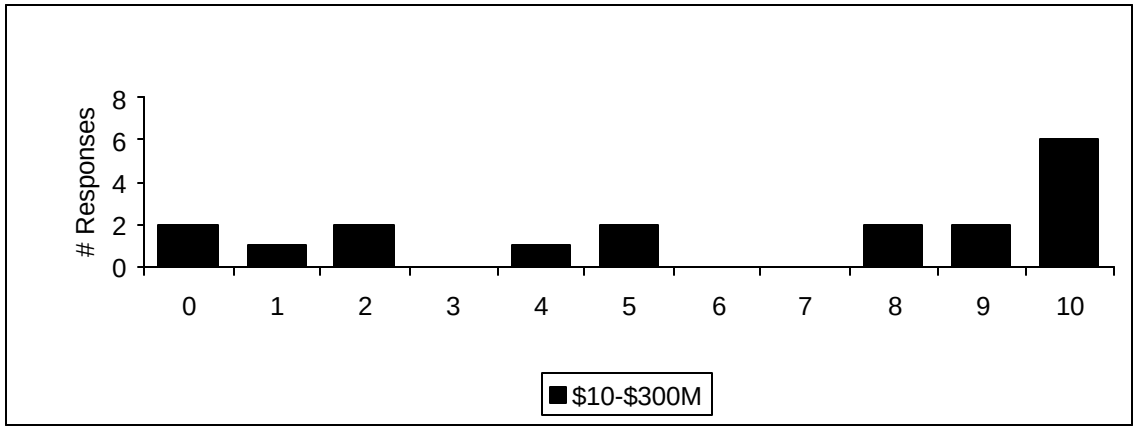


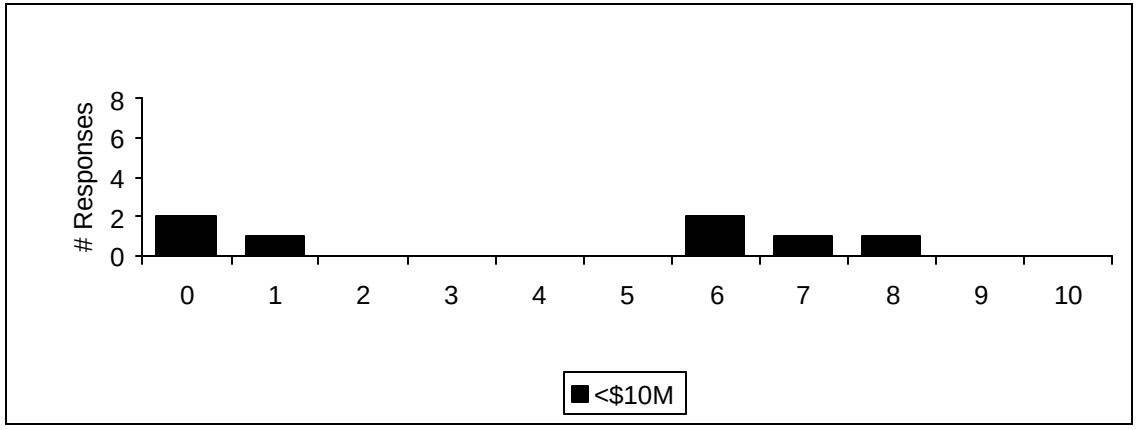
Differences By Company Size
(Continued)

Company size was also related to the level of respondents' awareness of the regulation itself. The answers on awareness were given on a scale of 0 – 10 where 0 is unaware and 10 is very aware.



These three graphs show, by company size, respondents' level of awareness of the details of the regulation's requirements for the retrieval of metadata or audit trails .

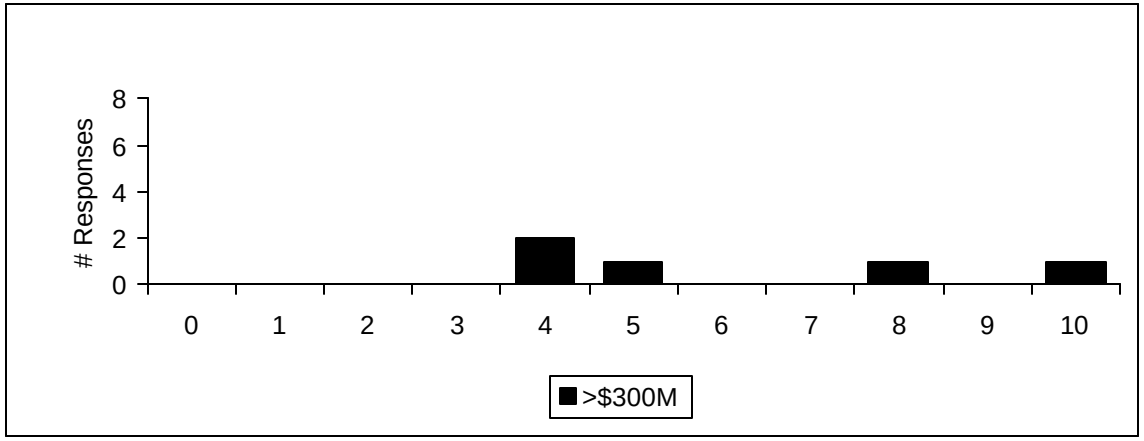


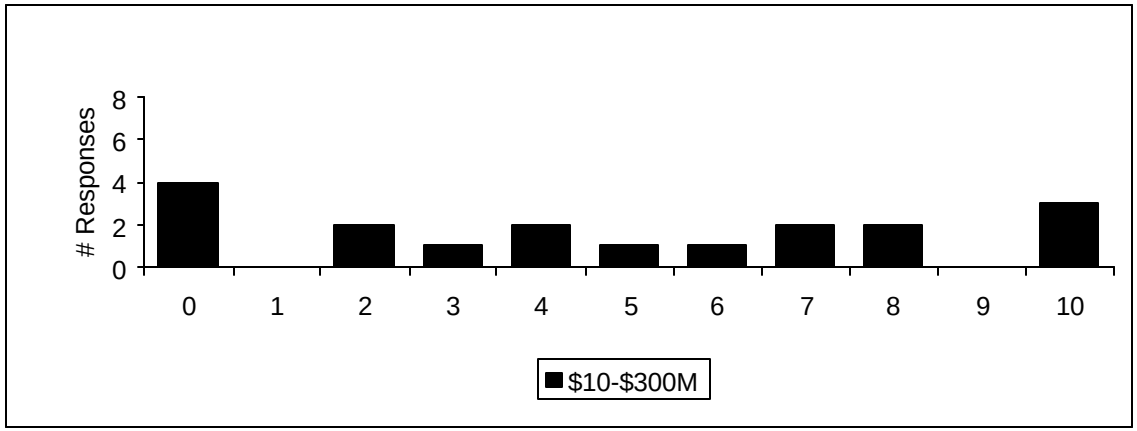


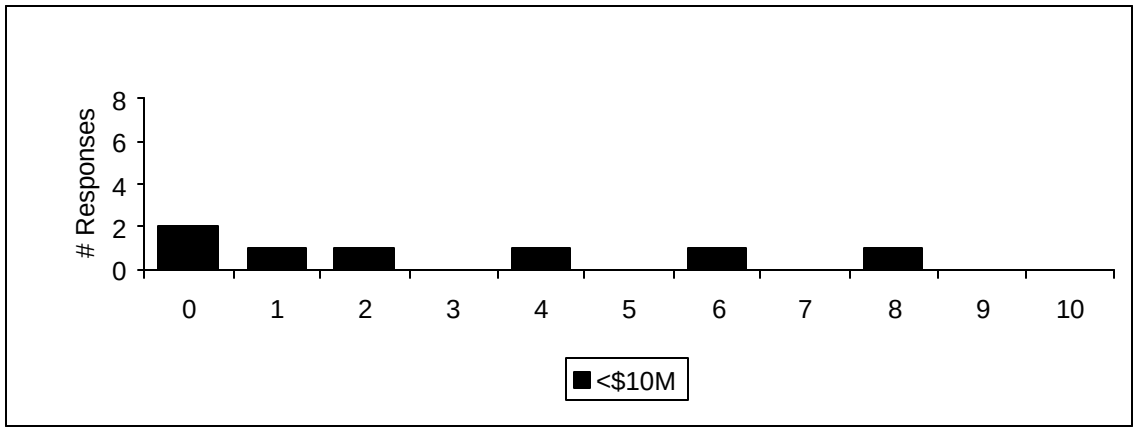
Differences By Company Size
(Continued)

Company size was related to respondents' level of awareness of the regulation itself. The answers on awareness were given on a scale of 0 – 10 where 0 is unaware and 10 is very aware.

These three graphs show, by company size, respondents' level of awareness of the details of the regulation's requirements to read electronic records and raw data in their original form.

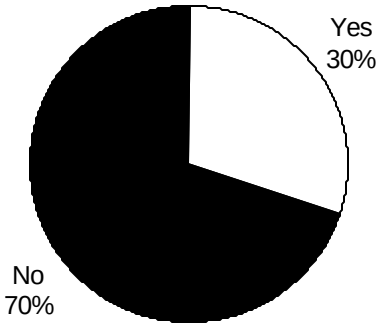




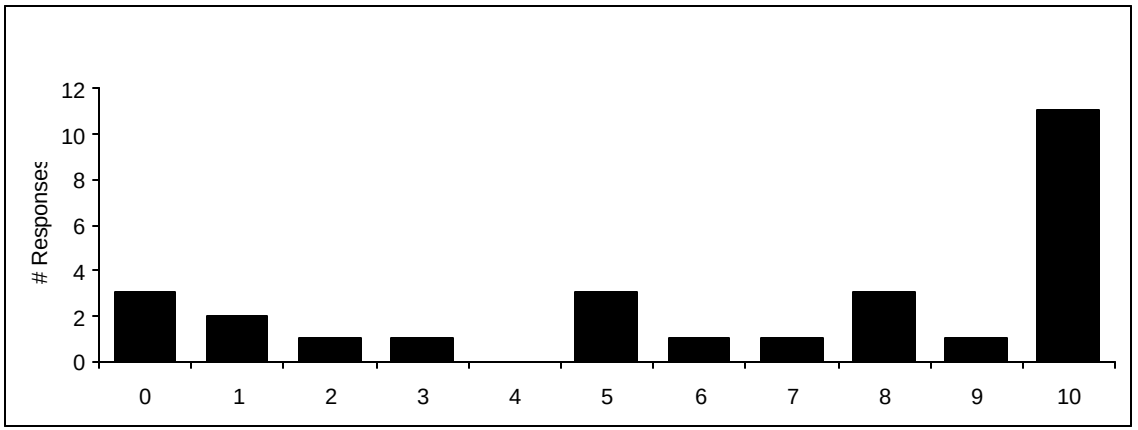


Electronic Signatures

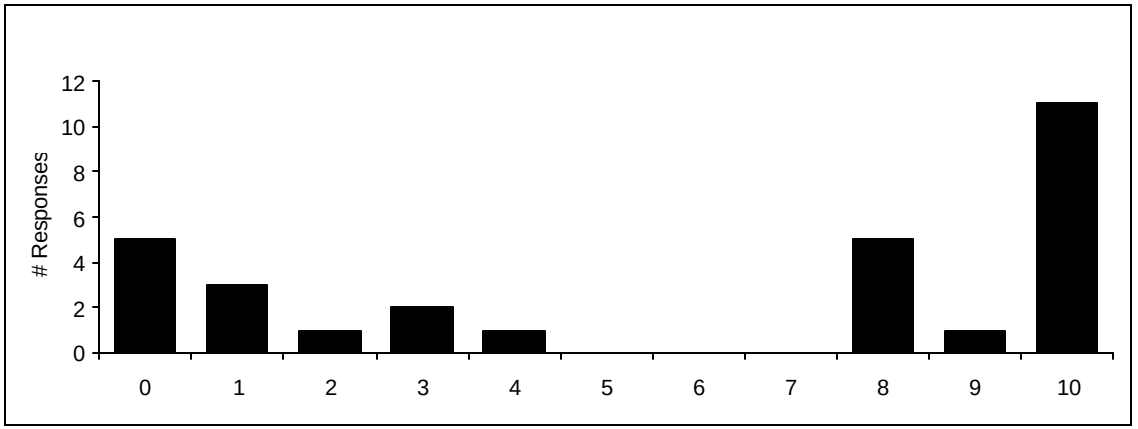
This pie chart depicts the current use of electronic signatures at the companies participating in the survey.



This graph shows respondents' level of awareness of the details in the regulations about the retrieval of electronic signatures. The answers on awareness were given on a scale of 0 – 10 where 0 is unaware and 10 is very aware.



This graph shows respondents' level of awareness of the details in the regulations about reading a retrieved electronic signature.

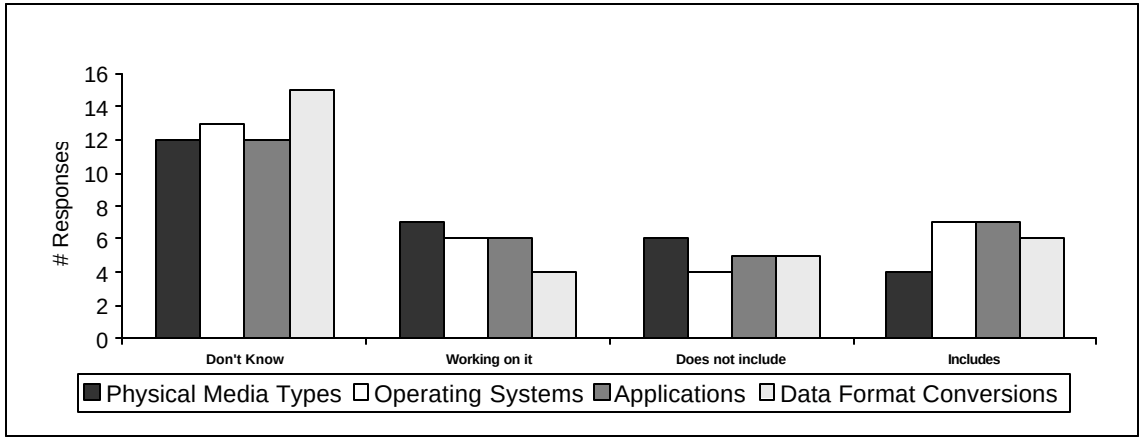


Planned Retention of Electronic Records

Plans for Long-Term Retention of Electronic Records

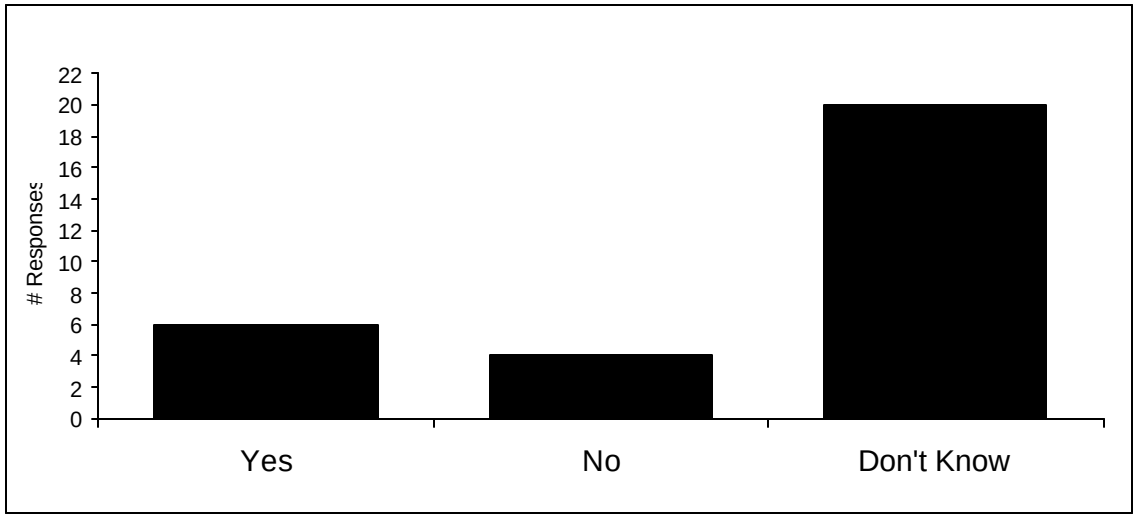
Respondents were asked about plans their companies have or are working on to deal with the long-term retention of electronic records and signatures.

This graph depicts current plans for the various aspects of retention, retrieval and reading of electronic records.



Retention of Operational Configurations

This graph shows respondents' assessment of whether companies need to retain an operational configuration (hardware, operating system, and application) in order to read electronic records and signatures in the future.



Methods for Retention of Electronic Records

The following table describes the methods planned for the long-term retention of electronic records and electronic signatures at the companies participating in the survey.

Methods to Retain	# Responses
Described the media on which electronic records would be stored.	18
Use off-site storage.	4
Have not figured out what to do yet.	5
Use back-ups to retain data.	4
Save old versions of hardware & software.	2
Duplicate on paper for long-term storage.	4
Archive the electronic data.	1

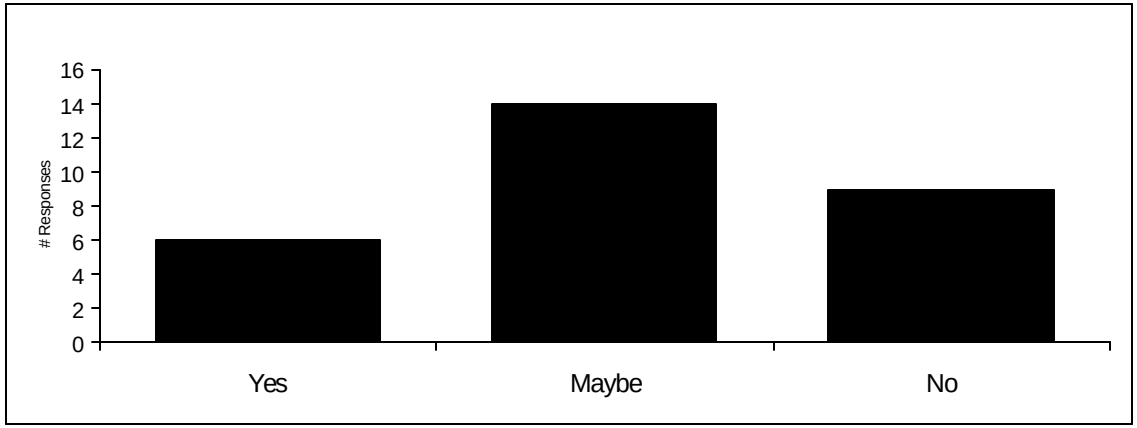
Company Needs for Long-Term Retention of Electronic Records

This table lists needs identified by the respondents for the long-term retention of electronic records and signatures.

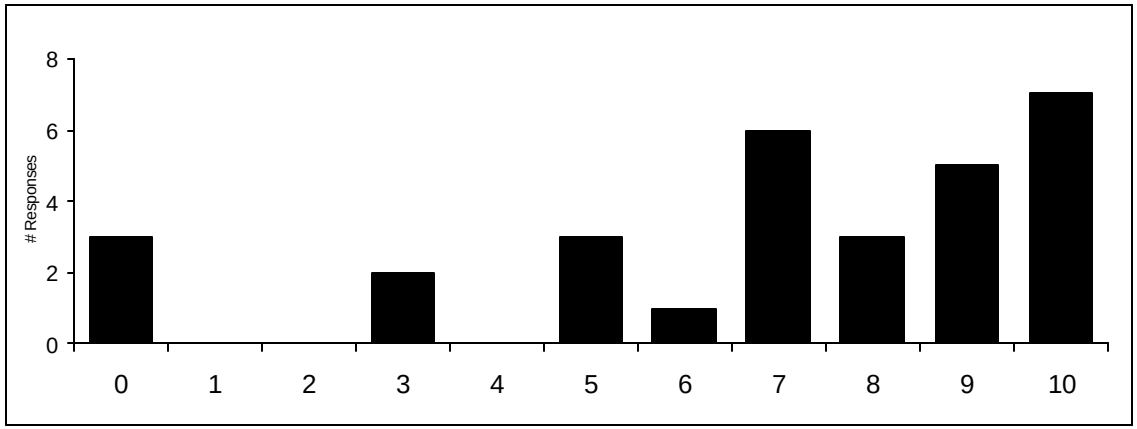
Needs	# Responses
Education and training on the regulation.	12
To find a technical solution for retaining and being able to read electronic records in the future.	5
Lots of money to solve the problem and implement a solution.	3
Guidance on how to develop and implement a solution.	3
Time and people to do the work.	3
Begin using electronic records and signatures.	3
Stay current with the regulations.	2
Management recognition of the severity of the problem.	2

Outsourcing Retention of Electronic Records

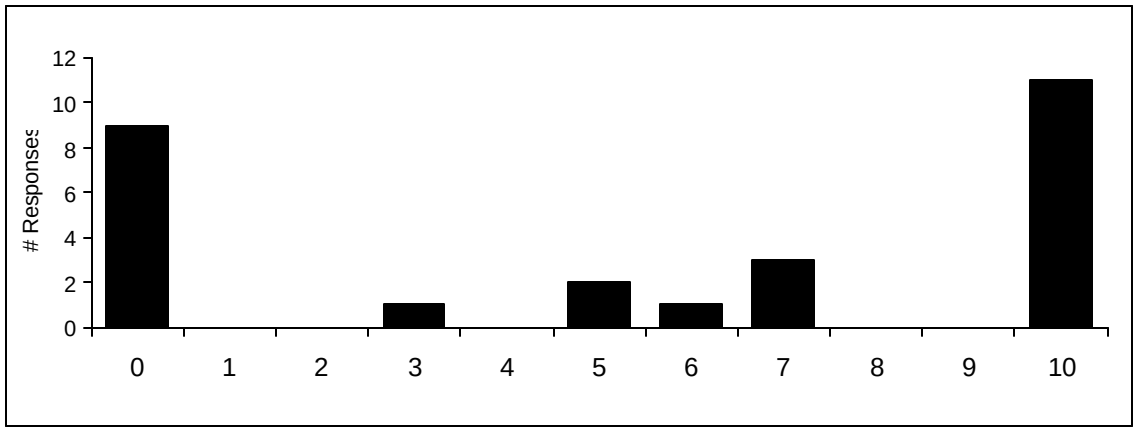
This graph shows the probability that the respondent's company would outsource the retention of electronic records; similar to what is currently being done for the retention for paper records.



This graph shows the respondent's perceived value of design and implementation assistance by qualified consultants. The answers were given on a scale of 0 – 10 where 0 indicates no perceived value and 10 indicates a great deal of perceived value.



This graph shows the likelihood that participating companies would outsource the retention of operational configurations, if they had to be retained. The answers were given on a scale of 0 – 10, where 0 indicates not likely and 10 indicates very likely.



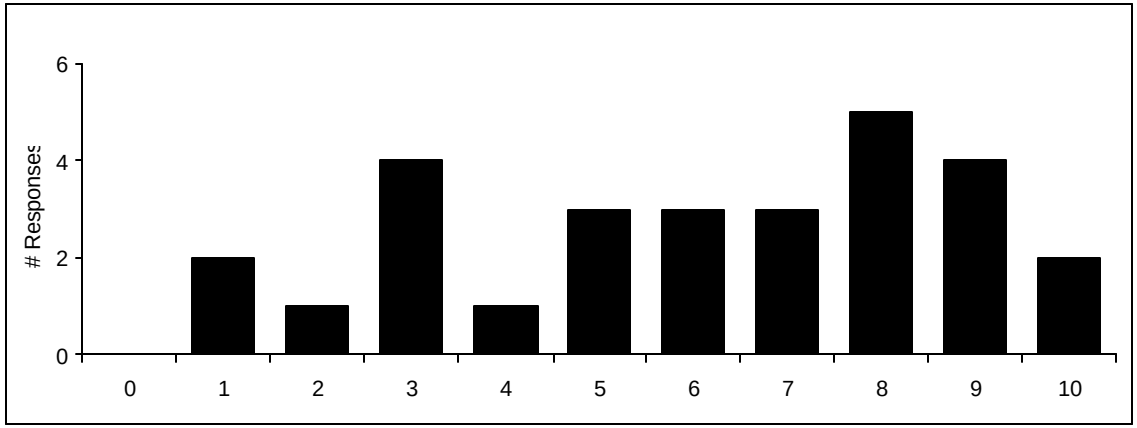
Outsourcing Retention of Electronic Records (continued)

The following table shows the percentage of participating companies likely to outsource.

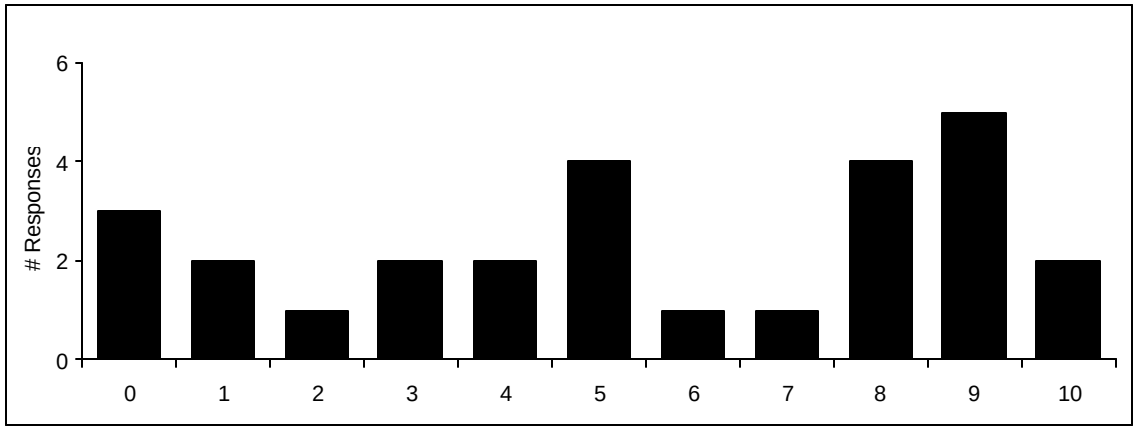
	No, would not outsource.	Might outsource	Yes, definitely would outsource.
Design Assistance	18%	32%	50%
Solution Implementation	10%	43%	47%
Data Conversion	24%	28%	48%
Retention of Electronic Records	33%	26%	40%
Retention of Operational Configurations	37%	22%	41%

Validation and Qualification of Computer Systems

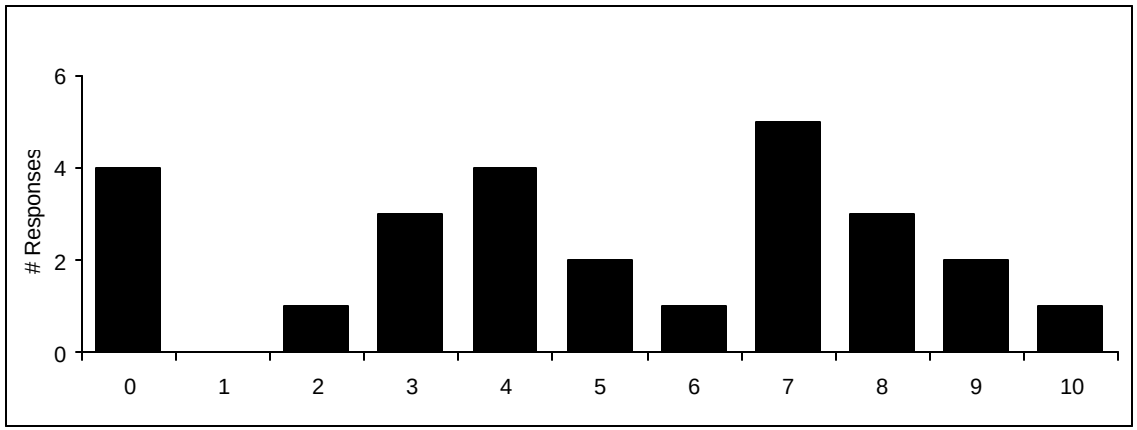
Respondents rated the quality of application validation within their company on a scale of 0 –10, where 0 was very poor and 10 was excellent.



Respondents rated the quality of the operating system validation within their company on a scale of 0 -10, where 0 was very poor and 10 was excellent.



Respondents rated the quality of the infrastructure (network, server, desktop PC's) validation within their company on a scale of 0 -10, where 0 was very poor and 10 was excellent.



Company Needs for Validation / Qualification

The following table describes needs identified by the respondents to attain validated computerized systems.

Needs	# Responses
Qualified validation personnel.	6
Training and knowledge on what to do for validation.	6
More people to do the work.	6
Plans to put validation into place.	3
Validate the computers and those used for laboratory instruments.	3
Stay current with regulations and good validation practices.	2
Time to do the validation work.	2
Don't validate computer systems, so we don't need anything.	2
Money to get the work done.	1